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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,531	06/30/2003	Subramanian S. Venkatraman	ARC 2869 N1	2177

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,531	VENKATRAMAN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-33 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-33 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 10/17/2005.

Claims 1-11, 34-53 have been canceled, and claims 54-56 have been added.

Claims 12-33 and 54-56 are pending and included in the prosecution.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12-33 and 54-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment has introduced a new matter that has not been described in the specification as originally filed. The claim has been amended to recite that "the polyurethane polymer has a glass transition

temperature such that it can be directly melt blended with the at least one drug". Nowhere in the specification applicants had disclosed glass transition temperature property of polyurethane polymer.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 12-20, 22, 33, 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Re 32,991 ('991) in view of US 6,010,715 ('715).

US '991 teaches polymer matrix for percutaneous application comprising active agent and a polyurethane elastomer TECOFLEX, which is the polyether polyurethane claimed by applicants formed by the reaction process of the same components (abstract; col.2, lines 63-68; col.3, lines 66-68; col.6, line 46; col.7, lines 49, 67). The drug forms 4% of the matrix (col.7, line 48). The modulus of the TECOFLEX is expected to be the same as the modulus of the polyurethane matrix claimed in claim 33. The melting temperature of the polyurethane polymer disclosed by the reference is expected to be the same as the claimed temperature of polyurethane polymer that has the same components, and the melting blend temperature of the of the polymer and drug expected to be the same depending on the drug. Furthermore, claim language "even without" and "can be" permits the presence of the solvent. The elastomer is strong yet flexible to conform to the shape of the site of application and have suitable viscosity that facilitates admixture with the drugs to form homogenous blend (col.2, lines 5-26).

However, US '991 does not teach the temperature at which a melt blend can be obtained, or the structure of the delivery device.

US '715 teaches a transdermal drug delivery device for controlled release of active agent to the skin or mucosa comprising laminate comprising backing layer, matrix layer formed from melt blend of the active agent and a polyether polyurethane polymer without a solvent, and means for affixing the laminate to the skin or mucosa (abstract; col.5, lines 10-25). The matrix comprises active agent such as narcotic analgesic in an amount of 2-10% and enhancer (col.14, line 18; col.20, lines 33, 49-51). The means for affixing the laminate to the skin is an adhesive layer that can be acrylate adhesive

(col.17, lines 14-16, 39-41). The reference discloses that melt blended matrix layer carrying the drug and the enhancer provides controlled release of the drug, eliminates the undesirable properties of solvents on the drug and the enhancers, and more economic because it requires less loading of the active agents to obtain the desired dosage release (col.7, lines 14-30).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a matrix for percutaneous application comprising active agent and a polyurethane elastomer as disclosed by US '991, and blend the mixture of the polymer and the drug without using solvent to obtain drug carrying layer in a drug delivery device as disclosed by US '715, motivated by the teaching of US '715 that the melt blended matrix layer carrying the drug and the enhancer provides controlled release of the drug, eliminates the undesirable properties of solvents on the drug and the enhancers, and more economic because it requires less loading of the active agents to obtain the desired dosage release, with reasonable expectation of having transdermal delivery device having a matrix formed of melt blend of polyurethane ether and a drug that provides controlled release of the drug, eliminates the undesirable properties of solvents on the drug and the enhancers, and more economic.

6. Claims 21, 23-29, 31, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '991 in view of US '715 as applied to claims 12-20, 22, 33 and 54-56 above, and further in view of US '6,139,866 ('866).

The teachings of US '991 and US '715 are discussed above. However, the references do not teach specifically fentanyl as the drug to be delivered from the melt blended matrix, or the specific permeation enhancers.

US '866 teaches percutaneous formulation to deliver fentanyl wherein the formulation is stable and has little irritation to the skin and excellent in percutaneous permeation of fentanyl (abstract). The formulation comprises 0.05-20% of fentanyl, 0.1-98% of PSA, and 0.01-20% of permeation enhancer such as glycerol monolaurate (col.1, lines 65-67; col.2, lines 1-2; col.4, lines 28-31, 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether and active agent as disclosed by US '991 in combination with US '715, and replace the narcotic analgesic disclosed by US '715 by fentanyl and the enhancer by glycerol monolaurate as disclosed by US '866, motivated by the teaching of US '866 that fentanyl can be delivered transdermally with little irritation to the skin and excellent percutaneous permeation, with reasonable expectation of having a transdermal device that deliver fentanyl from a melt blend matrix comprising polyurethane ether and glycerol monolaurate that has excellent permeation to fentanyl without skin irritation.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '991 in view of US '715 and US '866 as applied to claims 12-29, 31-33 and 54-56 above, and further in view of US 5,225,199 ('199).

The combination of US '991 with US '715 and US '866 does not specifically teach lauryl pyroglutamate as a permeation enhancer.

US '199 teaches plaster for transdermal drug delivery device to deliver active agents such as narcotic analgesics, wherein the plaster comprises polyurethane, drug and permeation enhancer such as lauryl pyroglutamate (abstract; col.7, lines 15-17, 22-24; col.14, lines 50, 62). The plaster enables the absorption of effective amounts of a drug with extremely reduced skin rash with no breakage or peeling of the skin (col.2, lines 22-27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane ether, fentanyl and enhancer as disclosed by US '991 in combination with US '715 and US '866, and replace the enhancer by lauryl pyroglutamate disclosed by US '199, motivated by the teaching of US '199 that the plaster comprising lauryl pyroglutamate enables the absorption of effective amounts of a drug with extremely reduced skin rash with no breakage or peeling of the skin, with reasonable expectation of having a transdermal device that deliver fentanyl from a melt blend matrix comprising polyurethane ether and lauryl pyroglutamate that has excellent permeation to fentanyl with minimal skin breakage or rash.

Response to Arguments

8. Applicant's arguments with respect to claims 12-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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